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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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ALSTON & BIRD LLP			LLOYD, EMILY M	
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			12/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/596,934	ROBERTS, PAUL R.	
	Examiner	Art Unit	
	Emily M. Lloyd	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 June 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>06/29/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

1. The drawings are objected to because they do not have uniform line width (including their labels). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.
2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "22" has been used to designate both small r.f. heat source and tip. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the

immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

3. The disclosure is objected to because of the following informalities: page 1 line 3 "an" should be inserted between "to" and "apparatus"; page 1 line 22 "The" should be added to the beginning of the line; page 2 line 12 "a" should be added before the word "connector"; page 3 lines 7-8 should be revised for clarity; page 5 line 10 "a" should be added after "include"; page 6 line 1 "an" should be added after "Such"; page 6 line 6 "A" should be added to the beginning of the line; page 6 line 9 "an" should be added after "Such"; and page 6 line 26 the dash should be deleted.

Appropriate correction is required.

Claim Objections

4. Claims 11-28 are objected to because of the following informalities: claim 11 should begin with the word "An" and claims 12-28 should begin with the word "The"; claim 15 should end with a period instead of a comma; and claim 27 line 2 "a" should be inserted before "position sensing apparatus". Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: the elements required to detect the location of electrical activity in the wall of a human bladder.

7. Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 18, it is unclear if the expandable device of claim 12 is also inflatable or if a second device is inflatable.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 11-14, 16-18, and 20-28 are rejected under 35 U.S.C. 102(b) as being anticipated by United States Patent 5662108 (Budd et al.).

Regarding claim 11, Budd et al. disclose an apparatus for detecting the location of electrical activity in the wall of a human bladder (electrophysiologic apparatus 10 Figure 1).

Regarding claim 12, Budd et al. disclose the apparatus according to claim 11 and comprising an expandable device (inflatable balloon 96 Figure 3; basket catheter 80 Figure 4) adapted for passage through the urethra in a collapsed condition and reversibly expandable when in the bladder (Column 8 lines 64-67).

Regarding claim 13, Budd et al. disclose the apparatus according to claim 12 wherein said expandable device has a plurality of detection sites thereon ("array or set of passive electrodes 48 typified by passive electrode 72" Column 5 lines 3-4 and Figure 3; "multiple passive electrode sites typified by electrode 84" Column 5 lines 23-24 and Figure 4).

Regarding claim 14, Budd et al. disclose the apparatus according to claim 13 wherein said detection sites are uniformly distributed on the surface thereof (Figure 4).

Regarding claim 16, Budd et al. disclose the apparatus according to claim 14 wherein said expandable device comprises a cage (basket catheter 80 Figure 4) having a plurality of arcuate arms (limb 82 Figure 4) extending between opposite poles (proximal and distal ends of central shaft 86 Figure 4).

Regarding claim 17, Budd et al. disclose the apparatus according to claim 12 and including an external telescopic connector whereby relative telescoping movement causes the device to expand and contract on demand (Column 8 lines 64-67; the device inherently can contract as it is also removable from the body).

Regarding claim 18, Budd et al. disclose the apparatus according to claim 12 and comprising an inflatable device (inflatable balloon 96 Figure 3).

Regarding claim 20, Budd et al. disclose the apparatus according to claim 12 and further including a fluid lumen (balloon catheter 94 Figure 3) adapted to permit filling of the bladder from the exterior (filling of balloon 96 Figure 3 would also fill the organ that the bladder is placed in).

Regarding claim 21, Budd et al. disclose the Apparatus according to claim 20 and comprising multiple lumens (balloon catheter 94 inherently has multiple lumens as fluid is allowed to travel to inflatable balloon 96 and electrical signals are passed through balloon catheter 94 as well).

Regarding claim 22, Budd et al. disclose the apparatus according to claim 11 and comprising an array of detection sites adapted to detect electrical activity in the wall of the bladder whereby the location of said electrical activity can be determined (Column 9 lines 18-27).

Regarding claim 23, Budd et al. disclose the apparatus according to claim 22 wherein said detection sites are uniformly distributed (Figure 4).

Regarding claim 24, Budd et al. disclose the apparatus according to claim 12 and further comprising orientation means whereby the orientation of an expandable device in the bladder may be determined from outside the bladder (Column 11 line 44 – Column 12 line 7).

Regarding claim 25, Budd et al. disclose the apparatus according to claim 12 and further including a lumen adapted to receive a stiff curved guide member for steering of the expandable device (a catheter such as balloon catheter 94 inherently has a lumen;

any lumen can receive a stiff curved guide member for steering it and such devices are well known in the art).

Regarding claim 26, Budd et al. disclose the apparatus according to claim 11 and further including an ablation tool (therapy catheter 18 Figure 3) adapted for insertion through the urethra and operable to ablate (delivery electrode 60 Figure 3 and Column 5 lines 17-18) the internal surface of the bladder wall.

Regarding claim 27, Budd et al. disclose the apparatus according to claim 26 wherein the tip of said tool (delivery electrode 60 Figure 16) is detectable by a position sensing apparatus (locator electrode 68 Figure 16).

Regarding claim 28, Budd et al. disclose the apparatus according to claim 27 wherein the tip of said tool is adapted to be electrically active (delivery electrode 60 Figure 3) and wherein said apparatus is adapted to detect said activity (Column 4 lines 42-50).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. Claims 15 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Budd et al.

Regarding claim 15, Budd et al. disclose the apparatus according to claim 14. Budd et al. do not disclose expressly that the expandable device resembles a sphere in the expanded state. Instead, Budd et al. discloses the expandable device resembles an oblate shape (inflatable balloon 96 Figure 3).

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to shape the expandable device of Budd et al. into a spherical shape because Applicant has not disclosed that shaping the expandable device into a sphere provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Budd et al.'s expandable device, and Applicant's invention, to perform equally well with either the shape taught by Budd et al. or the claimed spherical shape because both shapes would perform the same function of providing a plurality of detection sites equally well considering the typical size of human anatomy.

Therefore, it would have been prima facie obvious to modify Budd et al. to obtain the invention as specified in claim 15 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Budd et al.

Regarding claim 19, Budd et al. teach the apparatus according to claim 18 wherein said device includes an inflation lumen (balloon catheter 94 Figure 3) having an external closure (the lumen inherently has a closure to keep the material inflating the balloon 96 Figure 3 inside of the balloon; it would have been obvious to have this closure externally for easy physician control to allow the balloon to deflate easily).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily M. Lloyd whose telephone number is 571-272-2951. The examiner can normally be reached on Monday through Friday 8:30 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Emily M Lloyd
Examiner
Art Unit 3736

/EML/

A handwritten signature in black ink, appearing to read "Emily M Lloyd", written in a cursive style.